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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Reuben Matalon

Serial No.: 09/965,807

Group Art Unit: 1653

Filed: October 1, 2001

Examiner: Suzanne Marie Mayer

For: APARTOACYLASE GENE, PROTEIN, AND METHODS OF SCREENING FOR
MUTATIONS ASSOCIATED WITH CANAVAN DISEASE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97
and 1.98 as follows:

Timing and Fees

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information
disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA
under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT
application; OR
 - ☐ before the mailing of a first substantive office action (including after filing of an
RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods
specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

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is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☒ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
- ☒ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.
- ☐ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached.

Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
 - X = document of particular relevance when it is taken alone
 - Y = document of particular relevance when it is combined with another such document
 - A = document defining the general state of the art
 - O = non-written disclosure
 - P = intercalated document
 - T = document cited to understand the theory or principle underlying the invention
 - E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
 - D = cited in the application
 - L = cited for another reason
 - & = publication of member of same patent family
- ☐ Translation of other relevant information on foreign search report

Other Information

Since receiving the Notice of Allowance in the above-identified application, it has come to the attention of counsel that a reference cited in related and co-pending foreign applications had not been previously provided to the examiner on an Information Disclosure Statement. This reference, Matalon et al. *J. Inher. Metab. Dis.*, 12 Suppl. 2, 329-331, 1989, was cited in the application as reference No. 9, and includes authors who are also inventors of the pending application. On Page 331, lines 5-6, it was stated that "Aspartoacylase was purified to homogeneity from human and bovine brain" and cites this work as unpublished data by co-inventors Kaul and Matalon. This statement is similar and cumulative to statements already considered by the examiner, e.g.,

- "Furthermore, aspartoacylase from human brain and cultured skin fibroblasts ... follows a similar scheme of purification." (on Page 134 of Kaul et al, *J. Neurochem.*, 56:129-135, 1991; filed in the December 18, 2001 IDS and already considered by the examiner);
- "We have now purified aspartoacylase to more than 1,100 fold enrichment from

human and bovine brain ..." (from Kaul et al. 1988 abstract in the *American Journal of Human Genetics*; cited by the examiner in the §102(b) rejection in the Office action dated July 2, 2004, and subsequently overcome by applicants.

Thus, it is believed that the enclosed Matalon reference does not raise issues that have not already been considered by the examiner.

Also enclosed are Leong et al., Hagenfeldt et al., and D'Adamo et al. which were cited in the Information Disclosure Statement provided previously to the Patent Office, but inadvertently omitted. None of these three publications disclose purified human aspartoacylase.

Payment of Fees Due (If Any):

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Date: May 18, 2005

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

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|------------------------|-----------------|
| Application Number | 09/965,807 |
| Filing Date | October 1, 2001 |
| First Named Inventor | Matalon et al. |
| Group Art Unit | 1653 |
| Examiner Name | TBA |
| Attorney Docket Number | SHUTT 1-C1 |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | | Leong et al., <i>Methods in Enzymology</i> , 78: 87-101 (1981) | |
| Smu | | Kaul et al., <i>J. Neurochem.</i> 56 (1) 129-135 (1991) | |
| Smu | | Matalon et al., <i>Am. J. Med. Genet.</i> 29: 463-471 (1988) | |
| | | Adamo et al., <i>J. Neurochem.</i> 26 (4) 739-44 (1977) | |
| | | Hagenfeldt et al., <i>J. Inher. Metab. Dis.</i> 10 (2) 135-141 (1987) | |
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Examiner
Signature

Alyane M. Mayer

Date
Considered

18 June 2004

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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